IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Hideshi FUJIWAKE**

Group Art Unit: **1641**

Serial Number: **10/015,662**

Examiner: **Deborah A. Davis**

Filed: **December 17, 2001**

PTO Confirmation No.: **5139**

For: **AMINO ACID SEQUENCE DETERMINATION FOR PROTEIN OR THE LIKE**

Attorney Docket No.: **011658**
Customer No.: 38834

RESPONSE

MAILSTOP AF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

December 10, 2003

Sir:

In response to the Office Action dated August 26, 2003, applicants state as follows:

The Examiner's Rejection Under 35 U.S.C. §103

The Examiner has rejected claims 1-6 under 35 U.S.C. §103 as being unpatentable over ***Coull et al.*** (USP 5,011,861) in view of ***Rose et al.*** (Manual of Clinical Laboratory Immunology, Fourth Edition).

The Examiner first repeats the earlier rejection, finding that it would be obvious to treat the amino acids obtained by the Edman degradation according to the ***Coull*** patent, to a competitive assay according to the ***Rose*** article, to achieve Applicant's claimed method. In support of this position, the Examiner states that competitive assays "offer great specificity" and measure "relatively small molecules" in relatively small amounts.

Applicant has previously traversed this rejection by arguing that there is no motivation in either the ***Coull*** patent or the ***Rose*** article to modify the ***Coull*** determination to use an immunoassay step. The Examiner now replies that ***Coull*** is not limited HPLC amino acid determination, but also discloses a picric acid binding assay (22:25-37). The Examiner also states that the competitive binding assay of ***Rose*** acts with specificity and sensitively for ***relatively small molecules***. It is this latter disclosure, which the Examiner implies, would lead one skilled in the art to use such competitive amino acid determination tests.

Applicant's Response

Applicant's claimed invention is a method for determining the amino acid sequence of a protein or other peptide. The constitutive amino acids of the protein or other peptide are chemically cut and liberated "one by one" from the N end of the protein or other peptide. The liberated constitutive amino acids are identified by immunoassay using an antibody against a derivative of the constitutive amino acid.

Applicant respectfully traverses the rejection because the references would not provide one skilled in the art with a reasonable expectation of success. Specifically, Applicant believes that the combination to be unduly simplistic. The *Rose* article is quite general, referring to competitive assays for measuring "antigens or antibodies," more particularly "insulin and estrogen." The Examiner relies on the *Rose* article merely for the identification of competitive assays as one alternative type of test for measuring "small molecules."

But, what is meant in the reference by measurement of "small molecules?" Clearly the indication of the ***Rose*** article is that "insulin and estrogen" or analogous are

what is meant. Nothing is mentioned in the ***Rose*** article which would suggest a likelihood of success in measuring molecules as small as amino acids. Applicant therefore submits that the combination presented in the Office Action would not result in the claimed invention.

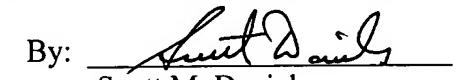
Conclusion

For at least the foregoing reasons, it is believed that this application is now in condition for allowance. If, for any reason, it is believed that this application is not in condition for allowance, Examiner is encouraged to contact the Applicants' undersigned attorney at the telephone number below to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP

By: 

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SMD/rer
Attachments: Petition for Extension of Time w/fee
Change of Correspondence Address